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Kären L. Knudson

Response #8

2/10/03 B Ross

RESPONSE			Docket No. **HOE002USPT01**
Serial No. **09/932,745**	Filing Date **August 17, 2001**	Examiner **Paradiso, John Roger**	Group Art Unit **3721**
Applicant:	**Hoekstra**		
Invention:	**CONTINUOUS WEB OF BREATHER POUCHES AND AUTOMATED METHOD OF PACKAGING MEDICAL DEVICES UTILIZING SUCH POUCHES**		

Box NON-FEE AMENDMENT
Commissioner of Patents
Washington, D.C. 20231

This Response is being filed in reply to the Office Action mailed October 4, 2002 to which a response is due on or before February 4, 2003 in light of the accompanying request for a one month extension of time.

No claims have been amended. No claims have been canceled. No new claims have been added. Claims 1-49 remain pending in the application.

As an initial matter, Applicant notes that the Office Action erroneously indicates that claims 1-45 are pending in the application. The application actually contains 49 claims (claims 1-37 contained in the application as originally filed and claims 38-49 added in a Preliminary Amendment filed November 12, 2001. For purposes of this response, Applicant has assumed that the Examiner intended to reject claims 1-49 as anticipated.

Objections/Rejections
Under 35 U.S.C. §102

3.0 *The Examiner has rejected claims 1-45 [49] over* ***Ivanov et al.***

SUMMARY OF CITED REFERENCES

Ivanov et al. discloses a microbial barrier vented package with superimposed gas impermeable first and second sheets. A plurality of cavities can be formed in the first sheet to define retention chambers for medical devices. A vent opening is provided through the second sheet and sealingly covered with a gas permeable microbial membrane (*e.g.*, TYVEK). Ivanov et al. discloses that the individual cavities can be cut from one another after each cavity has been filled, sterilized and sealed.

SUMMARY OF CLAIMED INVENTION

A **First Aspect of the Present Claimed Invention** (claims 1-13 and 46) is directed to an article of commerce comprising a longitudinally continuous web of superimposed first and second layers sealingly engaged along the lateral sides wherein the first layer comprises a gas permeable microbial barrier layer and the second layer comprises a thermoplastic gas impermeable layer. Longitudinally spaced laterally extending lines of weakness are provided in one of the first or second layer, and longitudinally spaced laterally extending lines of separation are provided in the other layer. The lines of separation are paired with the lines of weakness.

A **Second Aspect of the Present Claimed Invention** (claims 14-23 and 47) is directed to an article of commerce comprising a longitudinally continuous web of superimposed first and second layers sealingly engaged along one lateral end wherein the first layer comprises a gas permeable microbial barrier layer and the second layer comprises a thermoplastic gas impermeable layer. A longitudinally spaced series of paired laterally extending lines of weakness are provided in the first and second layers with the first and second layers sealed together along a pair of laterally extending seal

lines proximate each paired lines of weakness with the individual laterally extending seal lines in each pair of laterally extending seal lines separated by paired lines of weakness.

A **Third Aspect of the Present Claimed Invention** (claims 24-30 and 48) is directed to a method of packaging a medical device using a longitudinally continuous web defining a plurality of longitudinally spaced breather pouches, with each pouch comprised of superimposed first and second layers sealingly engaged along the lateral sides and the leading end. The first layer comprises a gas permeable microbial barrier layer and the second layer comprises a thermoplastic gas impermeable layer. Successive pouches are connected along laterally extending lines of weakness in the first layer.

A **Fourth Aspect of the Present Claimed Invention** (claims 31-37 and 49) is directed to a method of packaging a medical device using a longitudinally continuous web defining a plurality of longitudinally spaced breather pouches, with each pouch comprised of superimposed first and second layers sealingly engaged along both longitudinal sides and a first lateral end. The first layer comprises a gas permeable microbial barrier layer and the second layer comprises a thermoplastic gas impermeable layer. Successive pouches are connected along paired laterally extending lines of weakness in the first and second layers.

A **Fifth Aspect of the Present Claimed Invention** (claims 38-39) is directed to an article of commerce comprising a longitudinally continuous web of superimposed first and second layers sealingly engaged along the lateral sides wherein both the first and second layers are effective for preventing passage of microbes through the layer and at least the first layer is effective for permitting the passage of a sterilization gas. Longitudinally spaced laterally extending lines of weakness are provided in one of the first or second layer, and longitudinally spaced laterally extending lines of separation are provided in the other layer. The lines of separation are paired with the lines of weakness.

A **Sixth Aspect of the Present Claimed Invention** (claims 40-41) is directed to an article of commerce comprising a longitudinally continuous web of superimposed first

and second layers sealingly engaged along one lateral end wherein both the first and second layers are effective for preventing passage of microbes through the layer and at least the first layer is effective for permitting the passage of a sterilization gas. A longitudinally spaced series of paired laterally extending lines of weakness are provided in the first and second layers with the first and second layers sealed together along a pair of laterally extending seal lines proximate each paired lines of weakness with the individual laterally extending seal lines in each pair of laterally extending seal lines separated by paired lines of weakness.

A **Seventh Aspect of the Present Claimed Invention** (claims 42-43) is directed to a method of packaging a medical device using a longitudinally continuous web defining a plurality of longitudinally spaced breather pouches, with each pouch comprised of superimposed first and second layers sealingly engaged along and proximate both lateral sides and the leading end. Both the first and second layers are effective for preventing passage of microbes through the layer and at least the first layer is effective for permitting the passage of a sterilization gas. Successive pouches are connected along laterally extending lines of weakness in the first layer.

An **Eighth Aspect of the Present Claimed Invention** (claims 44-45) is directed to a method of packaging a medical device using a longitudinally continuous web defining a plurality of longitudinally spaced breather pouches, with each pouch comprised of superimposed first and second layers sealingly engaged along and proximate both longitudinal sides and a first lateral end. Both the first and second layers are effective for preventing passage of microbes through the layer and at least the first layer is effective for permitting the passage of a sterilization gas. Successive pouches are connected along paired laterally extending lines of weakness in the first and second layers.

THE IVANOV ET AL. REFERENCE DOES NOT DISCLOSE LINES OF WEAKNESS BETWEEN POUCHES

An anticipation rejection under 35 U.S.C. § 102 requires that the cited reference disclose each and every element of the claimed invention. *See,* Hybritech Inc. v. Monoclonal Antibodies,

Inc., 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); Kloster Speedsteel AB et al. v. Crucible Inc. et al., 230 U.S.P.Q. 81, 84 (Fed. Cir. 1986). Accordingly, the "exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference." Atlas Powder Co. v. E.I. duPont De Nemours & Co., 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984).

All Aspects of the Present Claimed Invention include the limitation of longitudinally spaced laterally extending lines of weakness in at least one of the layers forming the longitudinally continuous web. The Ivanov et al. reference does not disclose, teach or suggest lines of weakness in the layers forming the vented package.

CONCLUSION

Applicant respectfully submits that all pending claims (claims 1-49) are in condition for allowance.

Respectfully submitted,

Date 21 January 03 By _____

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